K083118
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510(k) Summary of Safety and Effectiveness

MAY 27 2009

Date Summary Prepared: October 20, 2008

Submitter Information: Spinal USA
2050 Executive Drive
Pearl, MS 39208

Contact Name: Jeffrey Johnson
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Device Trade Name: Spinal USA Anterior Cervical Interbody Fusion Device

Common Name: Intervertebral Body Fusion Device

Regulatory Number: 888.3080

Classification: Class II

Product Code: ODP

INTENDED USE:
The Spinal USA Interbody Fusion Device ACIF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Spinal USA Interbody Fusion Device ACIF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device. The device should be used with supplemental fixation.

DEVICE DESCRIPTION:
The Spinal USA Interbody Fusion Device ACIF System consists of implants with various heights to accommodate individual patient anatomy and graft material size. It is implanted from the anterior approach. It is to be packed with autogenous bone graft to facilitate fusion. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved. All components are manufactured from medical grade polyetheretherketone (Peek Optima, LT1). The products are supplied clean and "NON-STERILE".

PREDICATE DEVICE(S):
The predicate devices previously cleared by FDA are the Novel Cervical Spinal Spacer, Alphatec Spine (K081730), Crystal, Spinal Elements (K073351)

PERFORMANCE TESTING:
The pre-clinical testing performed indicated that the Spinal USA Interbody Fusion Device ACIF System is substantially equivalent to the predicate devices and is adequate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Spinal USA
% Mr. Jeffery Johnson
2050 Executive Drive
Pearl, Mississippi 39208

Re: K083118
Trade/Device Name: Spinal USA Anterior Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: April 20, 2009
Received: April 20, 2009

Dear Mr. Johnson:

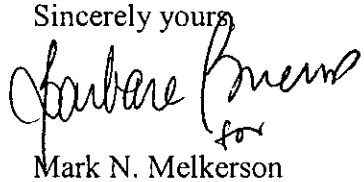
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K083118

Device Name: Spinal USA Anterior Cervical Interbody Fusion Device

Indication For Use:

The Spinal USA Interbody Fusion Device ACIF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Spinal USA Interbody Fusion Device ACIF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device. The device should be used with supplemental fixation.

Prescription Use __X___ AND/OR Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083118